Hip Contact Forces in Asymptomatic Total Hip Replacement Patients Differ from Normal Healthy Individuals: Implications for Preclinical Testing

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Abstract

Background. Preclinical durability testing of hip replacement implants is standardised by ISO-14242-1 (2002) which is based on historical inverse dynamics analysis using data obtained from a small sample of normal healthy individuals. It has not been established whether loading cycles derived from normal healthy individuals are representative of loading cycles occurring in patients following total hip replacement.

Methods. Hip joint kinematics and hip contact forces derived from multibody modelling of forces during normal walking were obtained for 15 asymptomatic total hip replacement patients and compared to 38 normal healthy individuals and to the ISO standard for pre-clinical testing.

Findings. Hip kinematics in the total hip replacement patients were comparable to the ISO data and the hip contact force in the normal healthy group was also comparable to the ISO cycles. Hip contact forces derived from the asymptomatic total hip replacement patients were comparable for the first part of the stance period but exhibited 30% lower peak loads at toe-off.

Interpretation. Although the ISO standard provides a representative kinematic cycle, the findings call into question whether the hip joint contact forces in the ISO standard are representative of those occurring in the joint following total hip replacement.

1. Introduction

The term “normal walking” is commonly referred to in hip implant testing, as simulators generally aim to reproduce the sliding distances and loads encountered in the body while walking. Walking has been chosen specifically as it is the most common activity where the bearing surfaces experience high loads and relative motion (sliding distance); both of these variables directly influence wear (Fisher and Dowson, 1991). The requirements for preclinical durability testing of total hip replacement (THR) implants are standardised by ISO-14242-1 (2002) which is intended to provide inputs defining a ‘representative’ cycle of normal walking in a typical individual. The data for the motion and load defined within the ISO standard for hip wear simulation was based on a historical inverse dynamics model using data obtained from normal healthy individuals (Paul, 1967). It is possible however that hip joint motion and loading patterns in patients following THR may differ from those of normal healthy individuals as a consequence of altered articulating surfaces and changes in soft tissues following reconstruction. It has been reported that THR patients exhibited a reduced gait velocity, a decreased hip mobility (Perron et al., 2000, Madsen et al., 2004) and altered muscle activity patterns (Long et al., 1993). Age has also been shown to influence the hip moment and power during gait (DeVita and Hortobagyi, 2000, Chester and Wrigley, 2008). The extent to which the ISO data are actually ‘representative cycles’ for hip joint loading has not been evaluated. Furthermore, recent attention placed on stratified approaches to treatment has highlighted the need to explore variability between groups even within existing standards (Bloss and Haaga John, 2013). Understanding the current test standard and future studies designed specifically to enhance future standards developments are likely in turn to improve pre-clinical testing.

We hypothesized in this exploratory study that the hip joint kinematics and contact forces of patients following THR may differ from healthy normal controls and from the ISO standard, with a view to determining whether future work might be of benefit.

2. Methodology

2.1 Clinical

Ethical approval was obtained in advance of the study from the Leeds West Ethics Committee. 15 asymptomatic unilateral total hip replacement patients were randomly selected for detailed motion analysis. Asymptomatic THR cases were defined by: no current symptoms in the index hip at the time of testing and no clinical indication of limping as determined by the surgeon, they were >12 months post-operation, were radiologically normal and had no other history of musculoskeletal disorders. All subjects had undergone hip replacement using an anterior approach. Although the specific implant used was not recorded and there was no formal quantification of functional ability, the cohort were representative of those cases who would be deemed clinically to have a good outcome. 38 normal healthy individuals from a dataset compiled using the same motion capture protocols were assigned to a normal cohort. Due to the large age difference between the ISO dataset (mean 19 years) and the anticipated age of our THR cases, the normal cohort was not actively age matched. Instead, subjects were targeted to represent normal function but to lie close to an age in which THR might be considered a surgical option.

2.1 Gait Analysis

Joint kinematics were recorded using a clinical gait analysis system comprising of an eight camera passive marker system (Vicon MX ,T40 cameras,150hz, Oxford Metrics, UK) with force plate data from two Bertec force pates (1000 Hz) (Bertec Corp, OH, USA). A 14 marker plug in gait model was used employing 9mm markers attached to the pelvis, thigh, shank and foot as well described previously (Holsgaard-Larsen et al., 2014), and the technical error for this setup within a working volume of 10 x 11 x 2.5 m was calculated as less than 0.2 mm. Following an acclimatisation period, gait data were acquired from three passes along an 8 metre walkway with clean strikes on the force plates observed.

2.3 Biomechanical Analysis

Motion capture and ground contact force plate data were imported into a multi-body dynamics modelling system (AnyBody, version 5.0, AnyBody Technology, Aalborg, Denmark) utilising inverse dynamics analysis. The musculoskeletal model of the lower extremity in AnyBody has been previously validated in the literature (Forster, 2004, Manders et al., 2008) and comprises of a human lower extremity model which includes 340 muscles and 11 rigid bodies representing talus, foot, shank, patella and thigh for both legs and the pelvis. The muscle, joint centre and inertial parameters of the lower extremity model in the AnyBody Repository is based on an anthropometric dataset provided by the University of

Twente (Horsman and Dirk, 2007). The trunk segments were included in this study for attaching the psoas major muscles, and were constrained to the pelvis.

For this study, simple muscle models without force-length-velocity relationships were adopted, as force-length-velocity relationships have been shown to have little influence on the prediction of muscle forces and contact forces of hip joints for normal gait (Anderson and Pandy, 2001). Model scaling and kinematic optimization were performed based on the marker trajectories of each file, reflecting individualized parameters for each participant. Ground reaction force was then applied to the foot segment of the scaled model to perform inverse dynamics analysis. The problem of muscle redundancy was solved by quadratic muscle recruitment (Heintz and Gutierrez-Farewik, 2007, Glitsch and Baumann, 1997) which minimizes the sum of muscle stresses squared. Hip contact force and hip moment for both legs of each subject were calculated after performing inverse dynamics analysis.

Gait parameters of the normal healthy cohort and the index limb of the THR patients were compared to the ISO data. The hip joint kinematics and joint loads for the operated and non-operated sides of THR patients were also compared to explore possible effects of unilateral THR on the contralateral limb. In the discussion, further comparison is made between the current results and previous in vivo data derived from instrumented hip prostheses. All comparisons of joint contact forces represent the total force magnitude and calculated joint contact forces were normalized to body weight to control for differences in body weight between subjects.

2.4 Statistical Analysis

Data are presented as mean values, along with the associated 95% confidence intervals (CI) for each cohort to show the variation within each cohort. Data sets were temporally aligned to 101 centiles through spline interpolation in MATLAB (R2013b, MathWorks, Natick, MA, USA). The means of the normal cohort were obtained by averaging the mean result of the two limbs for each subject. Because some of the gait data were not normally distributed, non-parametric statistical tests were used. A Mann-Whitney test was used to determine whether differences in kinematics and kinetics between cohorts were systematic and reached statistical significance, and the comparison between operated and non-operated limbs was conducted through a Wilcoxon test. A significance level $p \leq 0.05$ was regarded as significant throughout.

3. Results

The demographic characteristics of the control and asymptomatic cohorts are described in Table1. The velocity, cadence and stride length for the asymptomatic THR cohort was significantly reduced ($P < 0.005$) compared to normal healthy individuals (Table 2). The normal healthy individuals had significantly greater angular excursion in the directions of flexion/extension ($P = 5.7E-3$) and abduction/adduction ($P = 2.2E-5$) than the THR cohort (Table 3). Both groups demonstrated a characteristic peak-trough-peak (F_1– F_2– F_3) pattern in the hip contact force, however, this was significantly less dynamic in the asymptomatic THR patients whom exhibited a 22% higher trough ($P = 2.9E-3$) and 35% lower peak loads at toe-off ($P = 1.9E-8$) (Figure 1 and Table 3). Our normal cohort exhibited a very similar pattern and magnitude in kinetics to the ISO data. Using the same modern acquisition methods resulted in the THR cohort yielding 30% lower loads at toe-off (F_3). The differences in peak load at heel strike (F_1) were not significant for these three groups.

Within the asymptomatic THR cohort, there were no significant differences in any of the kinematic variables or predicted joint loading patterns between the operated and non-operated sides (Figure 2).

Within each cohort, between subject variability was higher (95% CI > 10% of the mean value) for hip abduction/adduction and internal/external rotation, although there was less between subject variability (95% CI < 10% of the mean value) in other parameters (Table 3). For the hip contact force, 95% CI were ~5% of the mean value for the normal healthy individuals and ~10% of the mean value for the asymptomatic THR cohort on both the operated and non-operated sides (Figure 1 and Figure 2).

4. Discussion

In this exploratory study, we hypothesized that the hip joint kinematics and contact forces of patients following THR may differ from healthy normal controls and from the ISO standard. Derived from the data by Paul, the ISO standard recommends a maximum load of 3kN, and is based on a 75kg patient and equates to a force of approximately four times body weight. A twin peak in the force time curves was predicted by the model with the average peak forces for the normal healthy cohort equalling 3.89 times body weight (mean BW = 72kG). Our data for the normal cohort was similar in shape and magnitude to the ISO standard (Table 3, Figure 3) which suggests that the traditional inverse dynamics used in the

ISO standard provided a comparable result to the modern acquisition and modelling techniques utilised in this study. As expected the normal healthy individuals recruited to this study were significantly older (mean 45 yrs.) than the subjects used in the inverse dynamics-calculated data published by Paul (mean 19 yrs.), and were arguably more representative of a THR patient although we accept that there was no attempt to match specifically to the THR cohort. Our normal cohort and THR cohort have similar age and BMI to typical healthy and THR populations respectively and thus are not closely matched for age and BMI. As reported by Bennett et al (2008), the difference in age alone would not be expected to account for the difference in gait kinematics between the normal healthy individuals and THR patients. However, other studies have reported age-affected alterations in gait parameters (DeVita and Hortobagyi, 2000, Chester and Wrigley, 2008) and so this warrants consideration. The mismatch in BMI may also be a reason for the difference in gait parameters between our normal healthy cohort and THR cohort. Better stratified studies are required in the future to further characterize the effect of age and BMI, although it was not within the scope of this study.

The novelty of this study was that the THR cohort consisted of unilateral asymptomatic THR patients, recruited at a minimum of one year post-operatively and who were carefully screened to have no other history of musculoskeletal disorders and to represent the typical THR patient in our regional tertiary referral centre, deemed to have a good clinical outcome. While the small sample investigated in this study makes the drawing of wide-ranging conclusions inappropriate, the presence of a systematic difference between our THR group and both the ISO cycle and the normal group suggest that further exploration of and development of testing standards might warrant further attention in future. Compared to the normal healthy individuals, there was evidence of a persisting decreased range of motion and reduced hip contact force in the THR patients which suggests that there is at least some residual compromise of function associated with hip arthroplasty even in cases with a clinically good outcome. This reduced mobility is in agreement with prior kinematic studies of THR patients in the literature (Loizeau et al., 1995, Bennett et al., 2008, Beaulieu et al., 2010, Madsen et al., 2004).

Contact forces were similar for the operated and non-operated side of the asymptomatic THR patients (Figure 2). The magnitude of the peak forces at heel-strike and to-off was similar to those reported by Foucher et al (2008) who reported values of 3.0 and 2.5 times body weight respectively. The reduced gait dynamics additionally led to a loss in the restoration of the second peak of force at toe-off perhaps related to diminished hip moment outputs (Table 3). As synovial joints are nearly frictionless (Mow and Lai, 1980, Jin et al., 1997, Li et al., 2013), the hip moment, which is related to the hip contact force, is generated mainly to balance ground reaction force and the inertia effect of the moving body segments. As such, hip moments are influenced by gait velocity, cadence and stride length, parameters that were all seen to reduce in asymptomatic THR patients. Consequently, the results confirm that even with carefully selected cohorts of patients exhibiting no other co-morbidities, the altered dynamic inputs observed in asymptomatic THR patients, as compared with the normal healthy individuals, lead to a corresponding reduction in hip range of motion and a lower joint contact force.

In vivo peak hip forces have been reported by several authors over the past 25 years using specialised instrumented prostheses with values ranging from 2.4 to 4.1 times body weight recorded during gait (Bergmann et al., 2001, Davy et al., 1988, Kotzar et al., 1991, Bergmann et al., 1993, Brand et al., 1994, Damm et al., 2013a, Damm et al., 2013b, Schwachmeyer et al., 2013). Whilst these reports are based on small numbers of patients, with varying degrees of postoperative recovery, the data provide useful information for comparison. The peak load predicted in this study was 3.35 times body weight (3.04 to 3.66) for the operated side which falls in the middle of the in vivo reported data from the literature.

The data published by Bergmann include more additional patient details that may be used for further comparison (Bergmann et al., 2001). Our asymptomatic THR cohort was comparable in age and BMI (64.27 yrs., 30.74) to those described by Bergmann (62.17 yrs., 29.05). A comparison of the average hip contact forces for the asymptomatic THR cohort are made to the in vivo measurements of Bergmann in Figure 3 on the operated side of implanted THR patients. There is some evidence of a bi-modalism in the four patients in the Bergmann dataset as some patients (HS, KW) had two distinct peaks of loading and a more dynamic pattern of gait, similar to our asymptomatic THR cohort, whilst others (PE, IB) had only a single peak possibly interpreted as being indicative of with poorer function. The strict patient selection criteria used in the current study allowed the authors to stratify an asymptomatic THR cohort that screened out poorly functioning patients. When considering the two patients of Bergmann with better function, our average joint force data was comparable during the majority of the gait cycle, although was ~20% greater at heel-strike. We acknowledge that direct comparison to existing datasets is difficult without the additional consideration of clinical data such as the involvement of multiple joints, contralateral THR or other functional compromise such as limb length inequality.

Although a surrogate only for direct measurement of joint forces, laboratory collection of kinematics and forces combined with multi-body dynamics facilitates the use of larger cohorts without the need for a specialised implant and the associated ethical challenges involved in instrumented joints. One weakness of the modelling approach, as exemplified in the current study, is that the individual patient geometry was derived by scaling a default patient model. Studies have been conducted investigating factors such as patient specific correction for hip centre, muscle architecture and muscle activation to refine multi-body dynamics solution. The effect on the resulting modelling has been widely discussed (Besier et al., 2003, Carbone et al., 2012) and we acknowledge that without controlling for these factors the current preliminary data must be interpreted with caution. Stansfield et al (2003) and Heller et al (2001) have compared the prediction of joint contact forces for small cohorts using multi-body dynamics against forces derived from direct measurement using instrumented prostheses for validation. These studies have shown that while multi-body dynamics provides an appropriate means of parametric analysis, it generally overestimates the peak joint contact forces by ~10%, due to the lack of a realistic muscle wrapping path around the hip joint within the model (Bergmann et al., 1993, Stansfield et al., 2003, Heller et al., 2001). While the current study set out only to explore tentatively the possibility that THR results in variance in joint loadings from the cycles applied in the ISO standard, any future evaluation should try to address such shortcomings.

For our THR cohort, who walk more slowly than healthy controls and have a higher BMI (BMI 27.7 to 33.8) than both the normal cohort and the general population, skin movement artefact may also be considered as important, although skin movement artefacts have been shown to be least sensitive to flexion/extension motions at angles seen in walking (Lu and O'Connor, 1999). In our study, flexion angle contributed the most to hip moment and the resultant contact force.

Our results suggest that the asymptomatic THR patients exhibited a similar hip range of motion but a different loading pattern when compared to the ISO standard, while the normal healthy individuals exhibited a similar loading pattern to that used in the ISO standard. The asymptomatic THR patients appeared to walk less dynamically, with significantly lower second peak contact forces and a significantly greater stance phase load. Whilst the THR patients examined in the study had reduced peak loads, the greater stance phase loads observed when combined with slower walking speeds will result in longer joint loading periods that may have a negative influence on bearing lubrication and subsequent wear. Additionally, many total hip replacement patients have concomitant multiple joint involvement or other functional compromises that will likely alter the kinetics and subsequent joint contact forces of the hip (Budenberg et al., 2012). Given the recent emphasis on stratified approaches to heath care interventions, these data support the argument for further work which might lead to better representation of the systematic variability of real-world in vivo conditions.

In conclusion, the hip contact force during gait in our sample of normal healthy individuals compared well with the ISO loading cycle, while the joint contact forces in the asymptomatic THR patients showed some differences from those used in the ISO standard. These preliminary data suggest that further work is warranted to explore whether THR patients more generally might differ from the ISO standard cycle, and also that future studies could benefit pre-clinical testing by exploring stratification according to differences in loading cycles more systematically.

Acknowledgements

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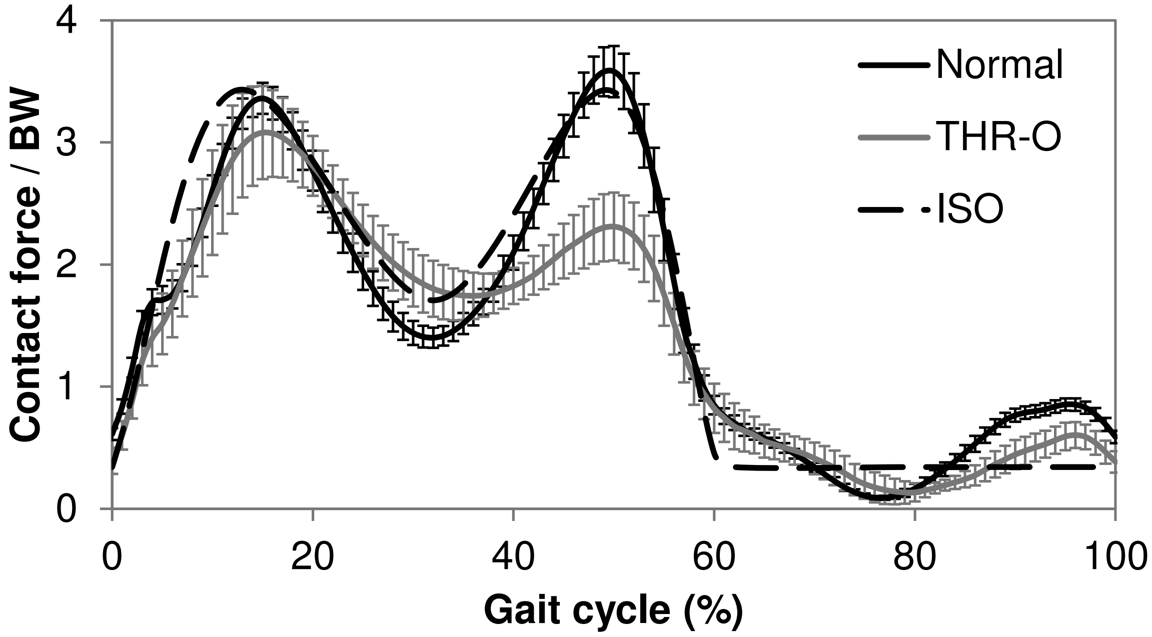
Figure 1. Mean joint contact forces ± 95% CI for the operated side of asymptomatic THR patients (THR-O) and normal healthy individuals (Normal), along with the ISO data. The loading pattern in ISO exhibited similar pattern and magnitude to the normal cohort but significantly differed from the THR cohort, with more dynamic pattern and higher magnitude, particularly on F_3.

Figure 2. Mean joint contact forces ± 95% CI for asymptomatic THR patients for the operated (-O) and non-operated (NO-) sides. Both sides of THR patients exhibited similar patterns and magnitude of hip contact force.

Figure 3. Mean joint contact force for the operated side of THR patients (THR-O, black line) and results of Bergmann for patients with instrumented THR prostheses (coloured lines) during normal walking (Bergmann et al., 2001). The predicted hip contact force for the operated side of THR patients was similar to patient HS and KW, but different from patient PE and IB in the results of Bergmann.

Figure 1.



Normal
THR-O
ISO
Contact force / BW
Gait cycle (%)
0
1
2
3
4
0
20
40
60
80
100

Figure 2.

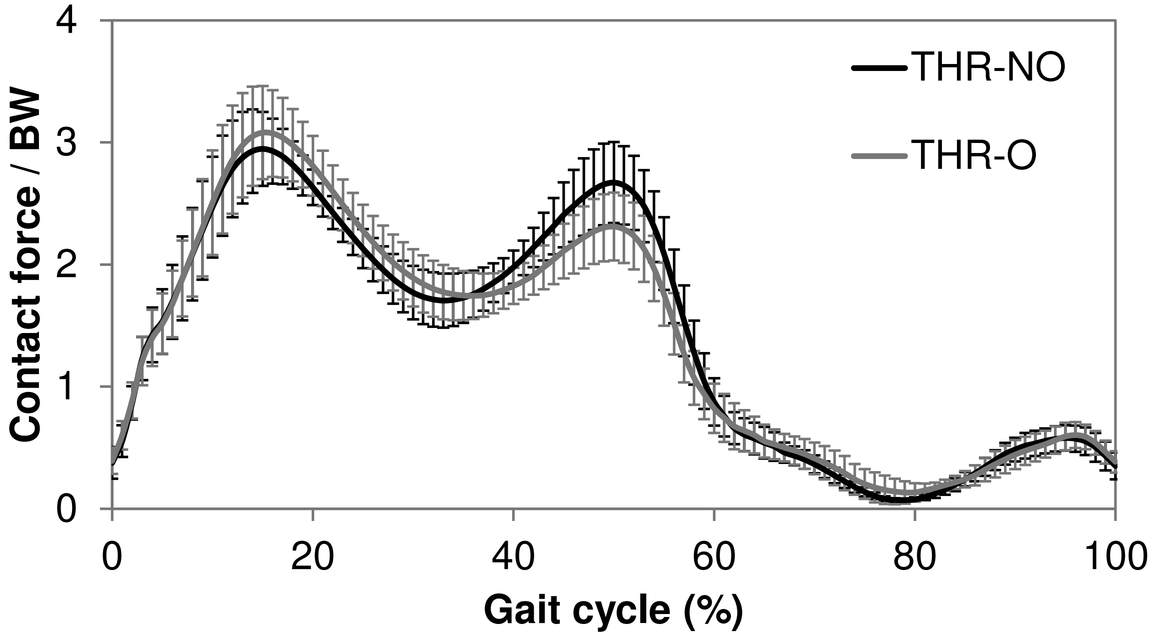
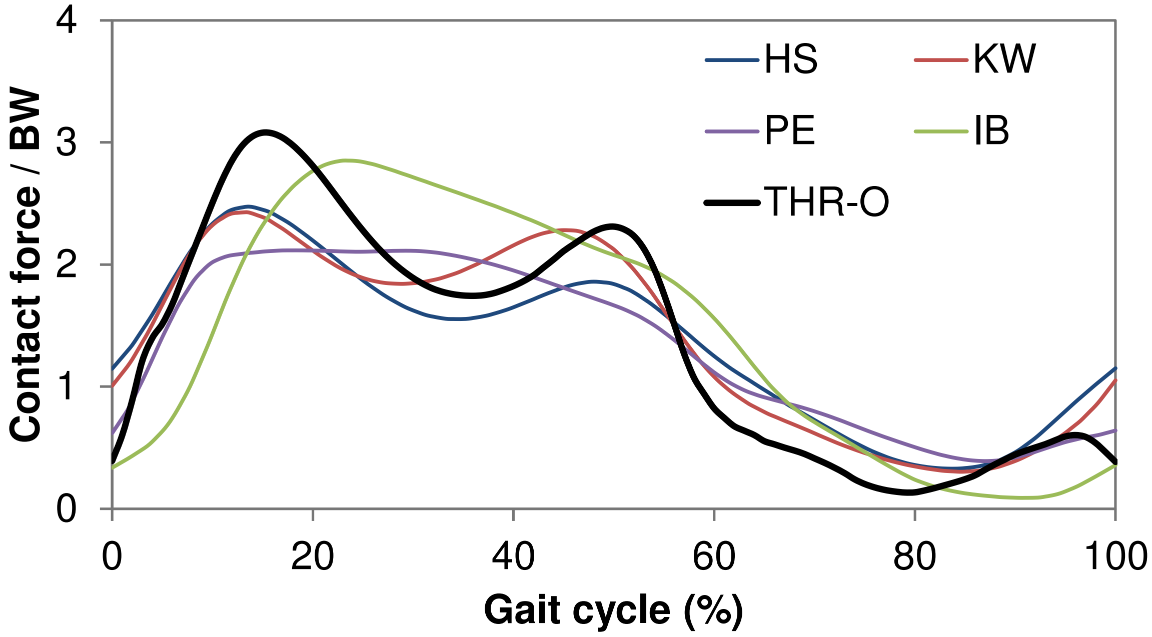


Figure 3.



Contact force / BW
Gait cycle (%)
0
1
2
3
4
0
20
40
60
80
100
HS
KW
PE
IB
THR-O

List of Tables

Table 1 Mean (95% CI) for gender, age and BMI in the control cohort and asymptomatic THR cohort.

Cohorts	Male / Female	Age (years)	BMI (kg/m^2)
Normal	19 / 19	44.97 (40.92 to 49.03)	24.72 (23.84 to 25.61)
THR	11 / 4	64.27 (58.59 to 69.95)	30.74 (27.72 to 33.77)

Table 2. Mean (95% CI) of gait velocity, cadence and stride length in the normal cohort and asymptomatic THR cohort. Values in these results were reduced for the THR cohort, compared to the normal cohort.

<table>
<tr><th></th><th>Velocity (m/s)</th><th>Cadence (steps/min)</th><th>Stride length (m)</th></tr>
<tr><td>Normal</td><td>1.44 (1.39 to 1.50)</td><td>121 (119 to 124)</td><td>1.43 (1.39 to 1.47)</td></tr>
<tr><td>THR-O</td><td rowspan="2">1.09 (1.01 to 1.18)</td><td rowspan="2">108 (104 to 112)</td><td>1.22 (1.13 to 1.32)</td></tr>
<tr><td>THR-NO</td><td>1.23 (1.13 to 1.32)</td></tr>
</table>

Table 3. Mean (95% CI) for hip contact force, hip moment, and kinematics (range of motion) for the ISO standard, the normal control cohort and asymptomatic THR cohort for the operated side.

	ISO	Normal	THR-O
F_1 (/ BW)	3.4	3.42 (3.30 to 3.55)	3.27 (2.94 to 3.61)
F_2 (/ BW)	1.7	1.33 (1.24 to 1.42)	1.62 (1.47 to 1.77)
F_3 (/ BW)	3.4	3.67 (3.46 to 3.89)	2.37 (2.11 to 2.63)
Moment at F_1 (/ BW×Ht)	N/A	0.0612 (0.0584 to 0.0641)	0.0646 (0.0569 to 0.0724)
Moment at F_2 (/ BW×Ht)	N/A	0.0201 (0.0183 to 0.0218)	0.0282 (0.0245 to 0.0318)
Moment at F_3 (/ BW×Ht)	N/A	0.0525 (0.0500 to 0.0550)	0.0379 (0.0344 to 0.0415)
Flexion/extension (^{o})	43	48.6 (47.1 to 50.2)	41.2 (37.52 to 44.9)
Abduction/adduction (^{o})	12	15.7 (14.4 to 17.0)	10.5 (8.9 to 12.1)
Internal/external rotation (^{o})	11	17.1 (15.4 to 18.8)	19.5 (15.0 to 24.0)

Note: Peak contact forces occur at slightly different times in the cycle for different individuals and hence the average normalised data in the Figures (averaged at the same time interval) is subtly different in magnitude to the average peak force in Table 3 that were taken at the time point of maximum force.